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| Form PTO-1449 INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION <i>(Use several sheets if necessary)</i> | | | Docket Number (Optional) MSA-009.01(20974-901) | Application Number 09/693,555 |
| | | | Applicant Kornman et al. | |
| | | | Filing Date October 20, 2000 | Group Art Unit 3736-1634 |

JUN 15 2001

U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
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| | AB US 4,656,127 | 04/07/87 | Mundy | 435 | 6 | JUN 20 2001 04/23/84 |
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| | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | Translation | |
|------|-----------------|----------|---------|-------|----------|--|----|
| | | | | | | YES | NO |
| CM | AT WO 91/02087 | 02/21/91 | PCT | | | English Abstract on the 1 st page | X |
| | AU WO 91/16452 | 10/31/91 | PCT | | | | X |
| | AV WO 92/15694 | 09/17/92 | PCT | | | | X |
| ↑ AW | WO 94/16101 | 07/21/94 | PCT | | | | X |
| ✓ AX | WO 97/06180 | 02/20/97 | PCT | | | | X |
| | AY WO 97/38135 | 10/16/97 | PCT | | | | X |
| CM | AZ WO 98/15653 | 04/16/98 | PCT | | | | X |

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| | | | Applicant Kornman et al. | |
| | | | Filing Date October 20, 2000 | Group Art Unit 3736 |
| CM | BA | WO 98/40517 | 09/07/98 | PCT |
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| OTHER DOCUMENTS | | | | |
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| CM | BC | Ahmed, et al.; "Major Histocompatibility Complex Susceptibility Genes for Dermatitis Herpetiformis Compared with Those for Gluten-sensitive Enteropathy", J. Exp. Med. 178: 2067-2075 (December 1993) | | |
| | BD | Blakemore et al.; "Interleukin-1 Receptor Antagonist Gene Polymorphism as a Disease Severity Factor in Systemic Lupus Erythematosus", Arthritis & Rheumatism 37 (9): 1380-1385 (September 1994) | | |
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| | BI | Collins et al.; "Effects of Porphyromonas Gingivalis Infection on Inflammatory Mediator Response and Pregnancy Outcome in Hamster", Infection and Immunity, 62 (10): 4356-4361 (Oct. 1994). | | |
| | BJ | Dinarello A. Charles, "Interleukin-1 and Interleukin-1 Antagonism", Blood 77 (8): 1627-1652, (April 15, 1991) | | |
| | BK | Dolan-Mullen et al.; "A Meta-analysis of Randomized Trials of Prenatal Smoking Cessation Interventions", Am. J. Obstet. Gynecol. 171: 1328-1334, (1994) | | |
| | BL | Eisenberg et al.; "Primary Structure and Functional Expression from Complementary DNA of a Human Interleukin-1 Receptor Antagonist", Nature 343: 341-346 (January 25, 1990) | | |
| | BM | Emmons et al.; "Development of Wound Infections Among Women Undergoing Cesarean Section", Obstetrics & Gynecology, 72(4): 559-564 (October 1988) | | |
| | BN | Ernest et al.; "Vaginal pH: A Marker of Preterm Premature Rupture of the Membranes", Obstetrics & Gynecology, 74(5): 734-737, (November 1989) | | |
| | BO | Gibbs et al.; "A Review of Premature Birth and Subclinical Infection", Am. J. Obstet. And Gynecol. 166 (5): 1515-1528 (May 1992) | | |
| | BP | Gratzner G. Howard.; "Monoclonal Antibody to 5-Bromo- and 5-Iododeoxyuridine: A New Reagent for Detection of DNA Replication", Science 218: 474-475 (October 1982) | | |
| CM | BQ | Gravett et al.; "Independent Associations of Bacterial Vaginosis and Chlamydia Trachomatis Infection with Adverse Pregnancy Outcome", JAMA, 256(14): 1899-1903 (Oct. 10, 1986) | | |

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Form PTO-1449

**INFORMATION DISCLOSURE CITE LIST
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Docket Number (Optional)
MSA-009.01(20974-901)Application Number
09/693,555Applicant
Norman et al.Filing Date
October 20, 2000Group Art Unit
3736

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CM BR Hillier et al.; "Association Between Bacterial Vaginosis and Preterm Delivery of a Low Birth-Weight Infant", The New England Journal of Medicine, 333(26): 1737-1742 (Dec. 28, 1995)

BS Hillier et al.; "A Case -Control Study of Chorioamnionic Infection and Histologic Chorioamnionitis In Prematurity", The New England Journal of Medicine, 319(15): 972-978 (Oct. 13, 1988)

BT Jacob O. Chaim; "Tumor Necrosis Factor α in Autoimmunity : Pretty Girl or Old Witch?", Immunology Today 16(3): 122-125 (1992)

BU Kaiser Jocelyn; "Med School Receive Hughes Windfall", Science 271: 138-140 (January 12, 1996)

BV Kent et al.; "The Effects of Interleukins 1 α and 1 β on Prostaglandin Production by Cultured Human Fetal Membranes", Prostaglandins 46: 51-59 (1993)

BW Lopez bernal; "Prostaglandins, Chorioamnionitis and Preterm Labour", British Journal of Obstetrics and Gynaecology, 94:1156-1158 (December 1987)

BX Mansfield et al.; "Novel Genetic Association Between Ulcerative Colitis and the Anti-Inflammatory Cytokine Interleukin-1 Receptor Antagonist", Gastroenterology 106: 637-642 (1994)

BY Martius et al.; "Relationship of Vaginal Lactobacillus Species, Cervical Chlamydia Trachomatis, and Bacterial Vaginosis to Preterm Birth", Obstetrics & Gynecology, 71(1): 89-95 (January 1988)

BZ Mazor et al.; "Changes in Amniotic Fluid Concentrations of Prostaglandins E₂ And F_{2 α} In Women with Preterm Labor", Israel Journal of Medical Sciences, 26(8): 425-428 (August 1990)

CA McDonald et al.; "Vaginal Infection and Preterm Labor", British Journal of Obstetrics and Gynaecology, 98: 427-435 (May 1991)

CB McDowell et al.; "A Genetic Association Between Juvenile Rheumatoid Arthritis and A Novel Interleukin-1 α Polymorphism", Arthritis and Rheumatism 38(2): 221-228 (February 1995)

CC McGregor et al.; "Antenatal Microbiologic and Maternal Risk Factors Associated with Prematurity", Am. J. Obst. Gynecol., 163: 1465-1473, (November 1990)

CD Minkoff et al.; "Risk Factors for Prematurity and Premature Rupture of Membranes: A Prospective Study of the Vaginal Flora in Pregnancy", Am. J. Obstet. Gynecol. 150: 965-972 (1984)

CE Mølvig et al.; "Endotoxin-Stimulated Human Monocyte Secretion of Interleukin 1, Tumour Necrosis Factor Alpha, and Prostaglandin E₂ Shows Stable Interindividual Differences", Scand. J. Immunol. 27: 705-716 (1988)CF Nicklin et al.; "A Physical Map of the Region Encompassing the Human Interleukin-1 α , Interleukin 1 β , and Interleukin-1 Receptor Antagonist Genes", Genomics 19: 382-384 (1994)

CG Newton et al.; "A Clinical and Microbiologic Analysis of Risk Factors for Puerperal Endometritis", Obstetrics & Gynecology, 75: 402- 406 (1990)

CH Offenbacher et al.; "Periodontal Infection as a Possible Risk Factor for Preterm Low Birth Weight", J. Periodontol. 67(10 Suppl.): 1103-1113, (October 1996)

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| | | Applicant Kornman et al. | RECEIVED |
| | | Filing Date October 20, 2000 | Group Art Unit 3736 |
| <p style="text-align: center;">JUN 15 2001</p> <p>CI Pociot et al.; "A TaqI Polymorphism in the Human Interleukin-1β (IL-1β) Gene Correlates with IL-1β Secretion in Vitro", European Journal of Clinical Investigation 22: 396-402 (1992)</p> <p>CJ Parant M.; "Possible Mediators in Endotoxin-Induced Abortion", Research in Immunology, 141:164-168 (1990)</p> <p>CK Pociot et al.; "Association of Tumor Necrosis Factor (TNF) and Class I Major Histocompatibility Complex Alleles with the Secretion of TNF-α and TNF-β by Human Mononuclear Cells: a Possible Link to Insulin-dependent Diabetes Mellitus", Europ. J. Immunol. 23: 224-231 (1993)</p> <p>CL Pociot et al.; "A TaqI Polymorphism in the Human Interleukin-1β (IL-1β) Gene Correlates with IL-1β Secretion in Vitro", European Journal of Clinical Investigation 22: 396-402 (1992)</p> <p>CM Probert et al.; "The Type I Interleukin-1 Receptor Acts in Series with Tumor Necrosis Factor (TNF) to Induce Arthritis in TNF-Transgenic Mice", European Journal of Immunology 25: 1794-1797, (1995)</p> <p>CN Romero et al.; "Amniotic Fluid Prostaglandin E₂ In Preterm Labor", Prostaglandins Leukotrienes and Essential Fatty Acids, 34:141-145 (1988)</p> <p>CO Romero et al.; "Interleukin-1 Stimulates Prostaglandin Biosynthesis by Human Amnion", Prostaglandins, 37(1): 13-22 (January 1989)</p> <p>CP Romero et al.; "Infection and Labor, III. Interleukin-1: A Signal for the Onset of Parturition", Am. J. Obstet. Gynecol. 160: 1117-1123, (1989)</p> <p>CQ Seckinger et al.; "A Urine Inhibitor of Interleukin 1 Activity Affects Both Interleukin 1α and 1β but not Tumor Necrosis Factor α^{II}", The Journal of Immunology, 139(5): 1541-1545, (September 1, 1987)</p> <p>CR Silver et al.; "Evidence Relating Bacterial Vaginosis to Intraamniotic Infection", Am. J. Obstet. Gynecol. 161: 808-812 (1989)</p> <p>CS Smoak, W. Ida; "Embryopathic Effects of the Oral Hypoglycemic Agent Chlorpropamide in Cultured Mouse Embryos", Am. J. Obstet. Gynecol. 169: 409-414, (1993)</p> <p>CT Tamatani et al.; "Existence of Both IL-1α and β in Normal Human Amniotic Fluid: Unique High Molecular Weight Form of IL-1β", Immunology 65: 337-342, (1988)</p> <p>CU Tarlow et al.; "Severity of Alopecia Areata is Associated with a Polymorphism in the Interleukin-1 Receptor Antagonist Gene", J. Invest. Dermatol. 103: 387-390, (1994)</p> <p>CV Vassali Pierre; "The Pathophysiology of Tumor Necrosis Factors", Ann. Rev. Immunol. 10: 411-452, (1992).</p> <p>CW Velden and Reitsma; "Amino Acid Dimorphism in IL-1α is Detectable by PCR Amplification", Human Molecular Genetics, 2 (10): 1753, (1993)</p> <p>CX Watts et al.; "Early Postpartum Endometritis: The Role of Bacteria, Genital Mycoplasmas, and Chlamydia Trachomatis", Obstetrics & Gynecology 73: 52-59 (1989)</p> <p>CY Watts et al.; "Bacterial Vaginosis as a Risk Factor for Post-Cesarean Endometritis", Obstet. Gynecol. 75: 52-58, (1990)</p> | | | |

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| <p style="text-align: center;">RECEIVED</p> <p>581 JUN 15 2001</p> <p>Wilson et al.; "An Allelic Polymorphism within the Human Tumor Necrosis Factor α Promoter Region Is Strongly Associated with HLA A1, B8, and DR3 Alleles", J. Exp. Med. 177: 557-560, (February 1993). JUN 20 2001</p> <p>DA Wilson et al.; "Genetics of Tumour Necrosis Factor-α in Autoimmune, Infectious, and Neoplastic Diseases", J. Immunol. 155: 1-12, (1995). TECHNOLOGY CENTER R3700</p> <p>DB Offenbacher et al.; "Periodontal Infection as a Possible Risk Factor for Preterm Low Birth Weight", J. Periodontol. 67: 1103-1113, (1996).</p> <p>DC International Search Report Completed on March 28, 2000 and mailed on July 04, 2000. Car</p> <p>EXAMINER: <i>Caro MCR</i> DATE CONSIDERED <i>5/20/02</i></p> <p>EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.</p> | | | |